510(k) Summary

Submitted by: Mid-Atlantic Diagnostics, Inc.
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DEC - 6 2010

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Contact: Susan Bush, Quality & Regulatory Affairs Manager

Date Submitted: November 8, 2010

Device Identification:

Trade Name: Cryopette™
Common Name: Cryopreservation container
Classification Name: Assisted Reproduction Labware (21 CFR 884.6160)
Product Code: MQK

Predicate Device: Irvine Scientific CryoTip (K041562)

Description:

The Cryopette consists of a cryostraw manufactured from polycarbonate-Lexan OQ-3820. This straw has a displacement bulb attached to one end of the cryostraw whose function is to aspirate and dispense the sample contained in the vitrification media in and out of the opposite (open) end of the cryostraw. The cryostraw is the only sample contacting portion of the Cryopette.

The metering sheath provides structural rigidity for the Cryopette. The support ring provides a backstop and seal for the displacement bulb. The outer case encases the displacement bulb to provide a surface for labeling.

The sealing mark, distal storage border and proximal storage border reference lines are found on the outside of the cryostraw.

Intended Use:

The Cryopette is a cryopreservation storage device that is intended for use in vitrification procedures to contain and maintain human blastocyst stage embryos.

Performance Data:

ADDITIONAL INFORMATION REQUESTED FOR CRYOPETTE 510(k) K100596

The following testing was performed:

1. Mouse Embryo Assay (MEA): >70% hatching at 96 hours
   MEA testing was performed to ensure that the Cryopette is nontoxic to embryos. Testing demonstrated that the hatching percentage well exceeded the specification of >70% at 96 hours, and this information will be provided on a Certificate of Analysis accompanying packages of the product.

2. Endotoxin (LAL) Levels: < 20 EU
   Endotoxin testing was performed to ensure that the Cryopette does not have unacceptable levels of endotoxin. Testing demonstrated that the endotoxin levels are <20 EU, and this information will be provided on a Certificate of Analysis accompanying packages of the product.

3. Mechanical Testing (Aspiration and Leakage)
   Mechanical testing, including evaluation of mean, minimum and maximum aspiration volumes, as well as leakage following heat sealing of the device, was performed on the Cryopette to ensure that the device functioned as intended. All testing demonstrated that the Cryopette aspirated samples appropriately and did not show evidence of leakage following heat sealing.

4. Blastocyst Survivability (comparative testing to CryoTip predicate device)
   Comparative testing was performed to demonstrate that mouse blastocysts had comparable survivability following various lengths of storage, compared to the predicate device. This testing demonstrated that mouse blastocysts vitrified and stored in Cryopettes had comparable survivability to mouse blastocysts vitrified and stored in CryoTips.

5. Heating and Cooling Rates (see table below)
   An independent laboratory conducted a comparative evaluation of the cooling and warming rates of media in the Cryopette and CryoTip. This testing demonstrated that the cooling and warming rates were equivalent.

6. Sterilization Validation: SAL 10^{-6}
   Sterilization validation was performed to demonstrate that the Cryopette had a SAL of 10^{-6}, and this information will be provided on a Certificate of Analysis accompanying packages of the product.

7. Shelf Life/Package Integrity
   Shelf life and package integrity testing was performed to demonstrate that the Cryopette maintains package integrity, sterility and functionality for the labeled shelf life of the devices.

Substantial Equivalence Comparison

SUBSTANTIAL EQUIVALENCE COMPARISON	MidAtlantic Diagnostics Cryopette (K100596)	Irvine Scientific CryoTip (K041562)
Indication for Use	The Cryopette is a cryopreservation storage device that is intended for use in vitrification procedures to contain and maintain human blastocyst stage embryos.	The CryoTip is a Cryopreservation device that is intended to be used to contain, freeze and maintain oocytes and/or embryos.
Method of Sterilization	Gamma irradiation 25 -35 kGy according to ISO EN552.	Gamma irradiation 25 -35 kGy according to ISO EN552.
Sterilization	Microbiological validation of 25kGy Radiation Sterilization by ANSI/AAMI/ISO 11137-2 Method VD max 25	Validation information not available
Sterility Assurance Level (SAL)	10^{-6}	10^{-6}
Testing- Endotoxin	LAL Method - Each lot of Cryopettes is tested for endotoxin levels. The level of endotoxin units per device must be less than the USP limit of 20EU/device.	LAL Method - Each lot of CryoTips tested for endotoxin levels. The level of endotoxin units per device must be less than the USP limit of 20EU/device.

Testing – Mouse Embryo Assay	**Each lot of Cryopettes is tested using one-cell mouse embryo bioassay. Results must be equal to or greater than 70% to blastocyst stage within 96 hours.**	**Each lot of CryoTips is tested using one-cell mouse embryo bioassay. Results must be equal to or greater than 70% to blastocyst stage within 96 hours.**
Type of Cryopreservation system	**Heat sealing capability allows for a closed system.**	**Heat sealing capability allows for a closed system.**
	MidAtlantic Diagnostics Cryopette (K100596)	**Predicate Device Irvine Scientific CryoTip K041562**
Blastocyst Survivability (Refer to Feb 2010 Submission)	**Overall survival of mouse blastocysts for the Cryopette was 96%.**	**Overall survival of mouse blastocysts for the Cryotip was 84%.**
Materials	**Cryo-Straw: polycarbonate Lexan OQ-3820** **Metering Sheath: stainless steel full hard T21-RW** **Support Ring: Black Delrin Acetal Resin** **Displacement Bulb: Elastosil LR 3003/20 US Silicon Rubber** **Outer Case: Pebax 6333 Tubing** **Adhesive: Loctite 3311** **Ink: 18696 Ink Grade (Black)**	**CryoTip: medical grade plastic** **Stainless steel cover sleeve**
Mean Sample Volume	**1.08 ul**	**1.50 ul**
Loading Method	**Samples loaded by gently depressing the displacement bulb to aspirate samples into the Cryo-Straw.**	**Samples loaded by attaching wide end of CryoTip to aspiration tool such as luer tip syringe using connector. Samples then aspirated into the CryoTip.**
Sample Placement	**Sample placement must be**	**Sample placement should be**

	between the Proximal and Distal Storage borders of the Cryopette.	**between 2nd and 3rd mark of the CryoTip.**
Mechanical Testing	**100% (61/61) of Cryopettes aspirated fluid as intended into the device. None of the Cryopettes experienced any clogging or leaking problems.** **The Cryopette succeeded 100% (61/61) of the time in delivering the specimen to the proper position within the device.** **Visual confirmation that 100% (61/61) Cryopettes had intact seals and no leakage of fluid.** **100% (61/61) Cryopettes remained intact after removing from liquid nitrogen.**	**100% (58/58) of Cryotips aspirated fluid as intended into the device. None of the Cryotips experienced any clogging or leaking problems.** **The Cryotip succeeded 100% (58/58) of the time in delivering the specimen to the proper position within the device.** **Visual confirmation that 100% (58/58) Cryotips had intact seals and no leakage of fluid.** **86% (50/58) Cryotips remained intact after removing from liquid nitrogen; 14% (8/58) Cryotips exploded immediately after removing from liquid nitrogen.**
Dimensions	**Cryo-Straw: 2.4"** **Bulb: .677"** **Distal end to sealing mark: .206"** **Sealing mark to Distal Storage border: .394"** **Distal storage border to proximal storage border: .394"** **Proximal Storage border to bulb: 1.406"** **I.D. of Bulb: .028"** **O.D of Bulb: .128"** **I.D. of Straw: .0100"** **O.D of Straw: .0150"** **Overall length: 3.067"**	**N/A** **N/A** **I.D of tip: .007"** **O.D of tip: .07"** **Overall length: 2.99"**
Dispensing Method Post Thaw	**Remove Cryopette® from liquid nitrogen and completely submerge entire**	**Remove Cryo Tip from liquid nitrogen and immerse into 37 degree Celsius**

	device into water at 37 degrees Celsius for 5 seconds. Wipe excess water off. Cryopette placed on cutting platform and cut is made just above the heat seal at the Sealing Mark. Displacement Bulb is then pressed to expel blastocyst(s) into vitrification warming media	**waterbath and swirl gently for 3 seconds. Wipe Cryo Tip with sterile wipe. Cut seal on wide end of Cryo Tip at Mark # 4. Attach wide end of Cryo Tip to appropriate aspiration tool. Slide metal cover sleeve up to expose tip end of Cryo Tip. Wipe tip with sterile wipe. Cut seal on Mark # 2 and dispense contents utilizing aspiration tool into vitrification warming media.**
Cooling Rate	**-23,700 °C/min**	**-12,000 °C/min**
Vitrification Method	**Sealed Cryopette is plunged into a liquid nitrogen reservoir and then placed in a goblet or cryocane. The CryoCane is then stored in a liquid nitrogen freezer for long term storage**	**Sealed Cryo Tip is plunged into a liquid nitrogen reservoir, metal covered side down, then placed in a goblet or CryoCane. The CryoCane is then stored in a liquid nitrogen freezer for long term storage**
Warming rate	**34,480 °C/min**	**24,000 °C/min**

Discussion of Similarities/Differences: Overall the Cryopette and CryoTip are very similar devices. Each consists of a Cryo-Straw with nearly identical dimensions and volume capacity. Each has a mechanism to aspirate fluid into the Cryo-Straw, heat seal the open ends of the Cryo-Straw, plunge the closed device into liquid nitrogen, and stored onto a CryoCane. The main two differences include the aspiration methods and the presence or absence of an outer metal sheath. The Cryopette has a built-in silicone bulb used to aspirate fluid into the Cryo-Straw whereas the CryoTip uses a detachable syringe. Both devices aspirate roughly the same volume of fluid just in a slightly different manner. The CryoTip incorporates an outer metal sheath that slides over the Cryo-Straw while being handled in storage whereas the Cryopette is stored without a metal cover. Mechanical testing to include Mouse Blastocyst Survival data demonstrate that each device consistently provides a high level of function as well as survival of blastocysts following vitrification and warming.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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DEC - 6 2010

Re: K100596
Trade Name: Cryopette®
Regulation Number: 21 CFR §884.6160
Regulation Name: Assisted reproduction labware
Regulatory Class: II
Product Code: MQK
Dated: November 18, 2010
Received: November 23, 2010

Dear Dr. Harvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100596

DEC - 6 2010

Device Name: Cryopette®

Indications for Use:

The Cryopette is a cryopreservation storage device that is intended for use in vitrification procedures to contain and maintain human blastocyst stage embryos.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D)

AND/OR

Over-the-counter use ____ (21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K100596